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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/587,653      | 06/05/2000  | David V. Sangar      | UTSG.231US          | 8912             |

7590 06/22/2004

Fubright & Jaworski LLP  
600 Congress Avenue Suite 2400  
Austin, TX 78701

EXAMINER

SCHEINER, LAURIE A

|          |              |
|----------|--------------|
| ART UNIT | PAPER NUMBER |
|----------|--------------|

1648

DATE MAILED: 06/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/587,653

**Applicant(s)**

SANGAR ET AL.

**Examiner**

Laurie A. Scheiner

**Art Unit**

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 28 May 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-56 is/are pending in the application.
- 4a) Of the above claim(s) 1-18, 22-26 and 34-50 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 19-21, 27-33 and 51-56 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

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Claims 1-18, 22-26 and 34-50 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 7. Claims 19-21, 27-33 and 51-56 are considered below. Appellants' brief is acknowledged. It is noted that a false representation of the facts of the case has been provided to the Office in the Petition of December 30, 2002. The Petition at page 3 of the arguments wrongly contends that SEQ ID NO:2 contains all of that which is set forth by SEQ ID NO:1, and the respective sequences therefore do not differ. Unfortunately, applicants provided false information to the Office in their Petition; upon which the decision favorable to applicants was granted. The sequence set forth by SEQ ID NO:2 does not contain all of the sequence set forth by SEQ ID NO:1 since the former is DNA while the latter is RNA.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 51-55 are rejected under 35 U.S.C. 112, second paragraph, as being vague and indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims are improperly drafted and confusing since SEQ ID NO:1 is an RNA while SEQ ID NO:2 is a DNA. Operability is problematic if applicants intend that the respective sequences are spliced. It is, however, unclear what applicants intend since they state in their arguments set forth in the Petition of December 30, 2002 that SEQ ID NO:2 encompasses completely the sequence as set forth by SEQ ID NO:1. Again, in *In re Steele*, 305 F.2d 859, 134 USPQ 292 (CCPA 1962), the court pointed out that before the claimed subject

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matter could properly be compared to the prior art, it was essential to know what in fact the claims did cover.

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 19-21, 27-33 and 51-56 are rejected under 35 U.S.C. 112, first paragraph, as being drawn to subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. *In re Rasmussen*, 650 F.2d 1212, 211 U.S.P.Q. 323 (C.C.P.A. 1981). The written description requirement under Section 112, first paragraph, sets forth that the claimed subject matter must be supported by an adequate written description that is sufficient to enable anyone skilled in the art to make and use the invention. The courts have concluded that the specification must demonstrate that the inventor(s) had possession of the claimed invention as of the filing date relied upon. Although the claimed subject matter need not be described identically, the disclosure relied upon must convey to those skilled in the art that applicants had invented the subject matter claimed. *In re Wilder, et al.*, 222 U.S.P.Q. 369 (C.A.F.C. 1984). *In re Werthheim, et al.*, 191 U.S.P.Q. 90 (C.C.P.A. 1976). *In re Driscoll*, 195 U.S.P.Q. 434 (C.C.P.A. 1977). *Utter v. Hiraga*, 6 U.S.P.Q.2d 1709 (C.A.F.C. 1988). *University of California v. Eli Lilly*, 119 F.3d 1559, 43 U.S.P.Q.2d 1398 (Fed. Cir. 1997). *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 U.S.P.Q.2d 1016-1031 (C.A.F.C. 1991). *Fiers v. Sugano*, 25 U.S.P.Q.2d 1601-1607 (C.A.F.C. 1993).

Applicants' disclosure fails to provide an adequate written description for the invention as broadly claimed. Essentially, the claims are drawn to a method of producing a virus comprising

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introducing into a cell a recombinant viral expression construct comprising encoding a 3' sequence of GBV. That is, the claims are drawn to a method of making virtually any construct so long as a 3' sequence (of at least 50 contiguous nucleotides) is incorporated therein. Is a recombinant GBV-B intended, a recombinant GBV-B/HCV chimera, a viable IRES chimera? Moreover, applicants appear to confuse an expression construct with a viable virus. A method for making **any** viable virus (comprising the 3' sequence limitation) is not enabled. What sequences, and in what gene order/and frame, in addition to the 50 contiguous nucleotides from SEQ ID NO:1 are intended? What virus is intended? The claims read on a method of making any virus having a GBV-B 3' sequence. Do applicants intend a method of making a recombinant HIV/GBV-B chimera? The pending claims do not in anyway correspond to what is taught in the specification. Applicants contend that they have provided SEQ ID NO:1 and methods of constructing an infectious GBV-B clone, a full length clone and the nucleotide sequence of the cloned GBV-B cDNA. The examiner contends that applicants do not claim a method of making an infectious GBV-B clone, nor do they claim a method of making a full length clone and the nucleotide sequence of the cloned GBV-B cDNA. Applicants claim a method of making a virus. As such, applicants' claims are drawn to making any virus so long as at least 50 contiguous nucleotides from SEQ ID NO:1 are included in some unknown insertion point, in some unknown vector. Again, a virus *per se* cannot be produced by a 3' portion of a viral genome. That is, an intact virus can be produced by expression of the entire viral genome only, providing that appropriate viral early proteins are available for processing. Applicants' disclosure fails to provide adequate written support for the invention as broadly claimed. As such, limiting the scope of the claims commensurate with that which has been described is required by the statute. As set forth in Lockwood v. American Airlines Inc., 107 F.3d 1565, 1571-1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997):

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It is the disclosures of the applications that count. Entitlement to a filing date does not extend to subject matter which is not disclosed, but would be obvious over what is expressly disclosed. It extends only to that which is disclosed. While the meaning of terms, phrases, or diagrams in a disclosure is to be explained or interpreted from the vantage point of one skilled in the art, all the limitations must appear in the specification. The question is not whether a claimed invention is an obvious variant of that which is disclosed in the specification. Rather, a prior application itself must describe an invention, and do so in sufficient detail that one skilled in the art can clearly conclude that the inventor invented the claimed invention as of the filing date sought. . . [A]ll that is necessary to satisfy the description requirement is to show that one is "in possession" of the invention . . . One shows that one is "in possession" of the invention by describing the invention, with all its claimed limitations, not that which makes it obvious. . . Although the exact terms need not be used in haec verba, . . the specification must contain an equivalent description of the claimed subject matter. [Citations omitted]

...  
It is not sufficient for purposes of the written description requirement of Section 112 that the disclosure, when combined with knowledge in the art, would lead one to speculate as to modifications that the inventor might have envisioned, but failed to disclose. Each application in the chain must describe the claimed features.


The specification must contain a written description of that which is now claimed. Fiers v. Revel, 984 F.2d 1164, 1170, 25 USPQ2d 1601, 1605 (Fed. Cir. 1993). Whether the disclosure(s) relied on "reasonably convey [ ] to the artisan that the inventor had possession at that time" of that which is now claimed is a question of fact. Again, applicants' claims are clearly broader than that which is described in the specification. Moreover, claims 51-55 are drawn to methods wherein the construct comprises both RNA and DNA which clearly has not been described.

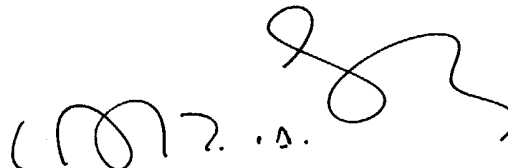
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laurie Scheiner, whose telephone number is (571) 272-0910. Due to a flexible work schedule, the examiner's hours typically vary each day. However, the examiner can normally be reached Monday thru Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached on (571) 272-0902.

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Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (571) 272-1600.

Correspondence related to this application may be submitted to Group 1600 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Official communications should be directed toward the following central fax number: (703) 872-9306.

  
Laurie Scheiner/LAS  
May 29, 2004

  
**LAURIE SCHEINER**  
**PRIMARY EXAMINER**